

**K210757 ETEST Fosfomycin (FO) (0.032-512 µg/mL)**Nov 12, 2021  
242 days to decisionK210757 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k210757/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Mar 15, 2021
Decision date	Nov 12, 2021
Days to decision	242 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biomerieux S.A.</b>
Location	Craponne, FR
Contact	Marine Taravant
510(k) history	16 submissions · 16 cleared · 2011-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210757/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026